IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WARNER-LAMBERT COMPANY LLC, and PF PRISM IMB B.V. Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, LTD, SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES, INC. Defendants.	C.A. No. _____

COMPLAINT

Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; and PF PRISM IMB B.V. (collectively, "Pfizer") file this Complaint for patent infringement against Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. (collectively, "Sun"), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Sun's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of IBRANCE® (palbociclib) capsules, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S. Patent No. 10,723,730 ("the '730 patent").

2. Sun Pharmaceutical Industries Ltd. notified Pfizer by letter dated September 22, 2020 ("Sun's Notice Letter") that it had submitted to the FDA ANDA No. 213107 ("Sun's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, and/or

sale of generic Palbociclib capsules, 75 mg, 100 mg, and 125 mg ("Sun's ANDA Product") prior to the expiration of the '730 patent. Sun's Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to Sun's ANDA. In an exchange of correspondence, counsel for Defendants and counsel for Sun discussed the terms of Sun's Offer of Confidential Access, though the parties were unable to agree on terms under which Pfizer could review the internal documents, data and/or samples relevant to infringement.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the holder of New Drug Application ("NDA") No. 207103 for the manufacture and sale of palbociclib capsules, 75 mg, 100 mg, and 125 mg, which has been approved by the FDA.

4. Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, New York 10017.

5. PF PRISM IMB B.V. is a private limited company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands.

6. Upon information and belief, defendant Sun Pharmaceutical Industries Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India. Upon information and belief, Sun Pharmaceutical Industries Ltd. is in the business

of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Sun Pharmaceutical Industries, Inc.

7. Upon information and belief, defendant Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Michigan with its principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. Upon information and belief, Sun Pharmaceutical Industries, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. Upon information and belief, defendant Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, with places of business at Office #43, Block Y, SAIF Zone, P.O. Box. No. 122304, Sharjah, United Arab Emirates, and DMCC Branch, 704 Jumeirah Business Center 1, Cluster G, JLT, P.O. Box No. 643561, Dubai, United Arab Emirates. Upon information and belief, Sun Pharma Global FZE is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

9. Upon information and belief, Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE are wholly owned subsidiaries of Sun Pharmaceutical Industries Ltd. Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. are collectively referred to herein as "Sun."

10. Upon information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. acted in concert to prepare and submit Sun's ANDA to the FDA.

11. On information and belief Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. know and intend that upon approval of Sun's ANDA, Sun Pharma Global FZE and

Sun Pharmaceutical Industries Ltd. will manufacture, market, sell, and distribute Sun's ANDA Product throughout the United States, including in Delaware. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Sun's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. participated, assisted, and cooperated in carrying out the acts complained of herein.

12. Upon information and belief, following any FDA approval of Sun's ANDA, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. will act in concert to distribute and sell Sun's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

13. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

14. Sun Pharmaceutical Industries Ltd. is subject to personal jurisdiction in Delaware because, among other things, Sun Pharmaceutical Industries Ltd., itself and through its wholly-owned subsidiaries Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun Pharmaceutical Industries Ltd., itself and through its subsidiaries Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore

transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Sun Pharmaceutical Industries Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Sun Pharmaceutical Industries, Inc. and Sun Global Pharma FZE, and therefore the activities of Sun Pharmaceutical Industries, Inc. and Sun Global Pharma FZE in this jurisdiction are attributed to Sun Pharmaceutical Industries Ltd.

15. Sun Pharma Global FZE is subject to personal jurisdiction in Delaware because, among other things, Sun Pharma Global FZE has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun Pharma Global FZE develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

16. Sun Pharmaceutical Industries, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun Pharmaceutical Industries, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

17. Sun has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described

in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

18. Upon information and belief, Sun, with knowledge of the Hatch-Waxman Act process, directed Sun's Notice Letter to Pfizer, an entity incorporated in Delaware, and alleged in Sun's Notice Letter that Pfizer's patents are invalid. Upon information and belief, Sun knowingly and deliberately challenged Pfizer's patent rights, and knew when it did so that it was triggering the forty-five day period for Pfizer to bring an action for patent infringement under the Hatch-Waxman Act.

19. Because Pfizer Inc. is incorporated in Delaware, Pfizer Inc. suffers injury and consequences from Sun's filing of Sun's ANDA, challenging Pfizer's patent rights, in Delaware. Upon information and belief, Sun knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Sun has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Sun's Notice Letter to Pfizer Inc., a Delaware corporation, that it would be sued in Delaware for patent infringement.

20. Upon information and belief, if Sun's ANDA is approved, Sun will directly or indirectly manufacture, market, sell, and/or distribute Sun's ANDA Product within the United States, including in Delaware, consistently with Sun's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Sun regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Sun's generic pharmaceutical products are

used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Sun's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Pfizer's patents in the event that Sun's ANDA Product is approved before the patent expires.

21. Upon information and belief, Sun derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Sun and/or for which Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE or Sun Pharmaceutical Industries, Inc. is the named applicant on approved ANDAs. Upon information and belief, various products for which Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, or Sun Pharmaceutical Industries, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

COUNT I – INFRINGEMENT OF THE '730 PATENT

22. Pfizer incorporates each of the preceding paragraphs 1–21 as if fully set forth herein.

23. The inventors of the '730 patent are Brian Patrick Chekal and Nathan D. Ide.

24. The '730 patent, entitled "Solid Forms of a Selective Cdk4/6 Inhibitor" (attached as Exhibit A), was duly and legally issued on July 28, 2020.

25. Pfizer is the owner and assignee of the '730 patent.

26. IBRANCE® is covered by one or more claims of the '730 patent, which has been listed in connection with IBRANCE® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

27. In Sun's Notice Letter, Sun notified Pfizer of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sun's ANDA Product prior to the expiration of the '730 patent.

28. In Sun's Notice Letter, Sun also notified Pfizer that, as part of its ANDA, Sun had filed a certification of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '730 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

29. On information and belief, Sun's ANDA Product and the use of Sun's ANDA Product are covered by one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

30. As an example, claim 1 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a primary particle size distribution characterized by a D90 value of from about 30 μm to about 65 μm.

31. On information and belief, Sun's ANDA Product infringes claim 1 of the '730 patent, literally or under the doctrine of equivalents.

32. Claim 7 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 40 μm.

33. On information and belief, Sun's ANDA Product infringes claim 7 of the '730 patent, literally or under the doctrine of equivalents.

34. Claim 15 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 30 μm.

35. On information and belief, Sun's ANDA Product infringes claim 15 of the '730 patent, literally or under the doctrine of equivalents.

36. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product before the expiration of the '730 patent was an act of infringement of the '730 patent under 35 U.S.C. § 271(e)(2)(A).

37. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

38. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

39. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '730 patent.

40. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '730 patent when Sun's ANDA is approved, and plans and intends to, and will,

do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

41. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '730 patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Sun's ANDA.

42. Notwithstanding Sun's knowledge of the claims of the '730 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '730 patent.

43. The foregoing actions by Sun constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

44. On information and belief, Sun has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730 patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

45. Pfizer will be substantially and irreparably harmed by infringement of the '730 patent.

46. Unless Sun is enjoined from infringing the '730 patent, actively inducing infringement of the '730 patent, and contributing to the infringement by others of the '730 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '730 PATENT

47. Pfizer incorporates each of the preceding paragraphs 1–46 as if fully set forth herein.

48. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '730 patent, and/or the validity of the '730 patent.

49. In Sun's Notice Letter, Sun notified Pfizer of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sun's ANDA Product prior to the expiration of the '730 patent.

50. In Sun's Notice Letter, Sun also notified Pfizer that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '730 patent. On information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that that '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product.

51. On information and belief, Sun's ANDA Product and the use of Sun's ANDA Product are covered by one or more claims of the '730 patent.

52. As an example, claim 1 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a primary particle size distribution characterized by a D90 value of from about 30 µm to about 65 µm.

53. On information and belief, Sun's ANDA Product infringes claim 1 of the '730 patent, literally or under the doctrine of equivalents.

54. Claim 7 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 µm to about 40 µm.

55. On information and belief, Sun's ANDA Product infringes claim 7 of the '730 patent, literally or under the doctrine of equivalents.

56. Claim 15 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 µm to about 30 µm.

57. On information and belief, Sun's ANDA Product infringes claim 15 of the '730 patent, literally or under the doctrine of equivalents.

58. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon approval of its ANDA.

59. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product would infringe one or more claims of the '730 patent.

60. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '730 patent.

61. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '730 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

62. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '730 patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Sun's ANDA Product.

63. Notwithstanding Sun's knowledge of the claims of the '730 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Product with its product labeling following FDA approval of Sun's ANDA prior to the expiration of the '730 patent.

64. The foregoing actions by Sun constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

65. On information and belief, Sun has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730

patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

66. Pfizer will be substantially and irreparably damaged by infringement of the '730 patent.

67. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Sun's ANDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '730 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '730 patent, and that the claims of the '730 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that the '730 patent has been infringed under 35 U.S.C. § 271(e)(2) by Sun's submission to the FDA of Sun's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sun's ANDA Product, or any other drug product that infringes or the use of which infringes the '730 patent, be not earlier than the expiration date of the '730 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sun, and all persons acting in concert with Sun, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Products, or any other drug product covered by or whose use is covered by the '730 patent, prior to the

expiration of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Sun's ANDA Products, or any other drug product which is covered by or whose use is covered by the '730 patent, prior to the expiration of that patent, will infringe, induce the infringement of, and contribute to the infringement by others of, said patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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